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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/778,516	02/07/2001	Wei-Yu Lo	12875-002001 / 0643-5299U	3185
26161	7590	07/22/2004	EXAMINER SULLIVAN, DANIEL M	
FISH & RICHARDSON PC 225 FRANKLIN ST BOSTON, MA 02110			ART UNIT 1636	PAPER NUMBER

DATE MAILED: 07/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

389.

## Office Action Summary

Application No.

09/778,516

Applicant(s)

LO ET AL.

Examiner

Daniel M Sullivan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 14 May 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1, 7-12 and 14 is/are allowed.
- 6) ☒ Claim(s) 3, 13, 15 and 16 is/are rejected.
- 7) ☒ Claim(s) 2 and 4-6 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)          |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

**DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 14 May 2004 has been entered.

Claims 1-14 were considered in the Final Office Action mailed 10 September 2003. Claims 1 and 13 were amended, and claims 15 and 16 were added in the 14 May Paper. Claims 1-15 are presently pending and under consideration.

***Response to Amendment***

Claim 13 stands rejected under 35 U.S.C. § 112, first paragraph, as lacking enablement for reasons of record and herein below in the "Response to Arguments".

Rejection of claims 1-3, 5, 6 and 10-14 under 35 U.S.C. 112, first paragraph, as lacking adequate written description for the claimed subject matter is withdrawn in view of the amendments to the claims. The claim has been amended such that the nucleic acid sequence encoding a protein which is involved in replication of the lactic acid bacterial plasmid is limited to encoding a RepA protein, which is described in the specification at page 7, line 23-28 and the Bouia *et al.* (1989) *Plasmid* 22:185-192 reference cited therein.

***Response to Arguments***

Claim 13 is rejected as lacking enablement for a DNA vaccine composition comprising the broad scope of “an antigenic gene”. In response to the *prima facie* case and arguments of record, Applicant has amended the claim such that it is now limited to an immunogenic composition rather than a vaccine. However, upon reviewing the specification, the Examiner can find no asserted use for an immunogenic composition according to the claim other than as a vaccine. Thus, using the claimed invention according to the teachings of the specification requires that the composition be capable of eliciting an immune response of sufficient magnitude to provide vaccination. For reasons of record, the disclosure fails to provide enablement for the broad scope of immunogenic compositions comprising an antigenic gene, wherein said immunogenic compositions are useful as vaccines. Therefore, claim 13 stands rejected under 35 U.S.C. §112, first paragraph, as lacking an enabling disclosure.

***New Grounds*****Specification**

The disclosure is objected to because of the following informalities: The specification contains sequence disclosures that are not identified by SEQ ID NO (*e.g.*, page 14, lines 24-25 and page 15, lines 16-17). Applicant is urged to carefully review the disclosure and provide SEQ ID NOs. for all sequences of greater than 10 nucleotides disclosed therein.

Appropriate correction is required.

### Claim Objections

Claims 2, 4, 5 and 6 are objected to because of the following informalities: The claims contain grammatical errors. Specifically, claim 2 is missing an article in line 2 (*i.e.*, the claim should read, ...promoter is a cytomegalovirus...). Likewise, claim 4, line 2 should read, ...replication is a Rep A protein...”; claim 5, line 2 should read, ...gene is a  $\beta$ -galactosidase...”; and claim 6, line 2 should read, ...gene is an erythromycin resistance gene... Appropriate correction is required.

### Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 15 and 16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The MPEP states, “[i]f new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. §112, first paragraph-written description requirement.

*In re Rasmussen*, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981).” (MPEP § 2163.06).

The MPEP further states, “[w]henver the issue arises, the fundamental factual inquire is

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whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in the application” (*Id.*, § 2163.02). The introduction of claim changes which involve narrowing the claims by introducing elements or limitations which are not supported by the as-filed disclosure is a violation of the written description requirement of 35 U.S.C. 112, first paragraph. See, e.g., *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1571, 39 USPQ2d 1895, 1905 (Fed. Cir. 1996).

In the instant case, the claims are directed to a Lac shuttle vector comprising a nucleic acid encoding a protein that consists essentially of the sequence of the RepA protein. However, the originally filed specification and claims do not disclose a sequence for the RepA protein. Thus, the limitation of the claimed subject matter to comprising a specific “sequence of the Rep A protein” constitutes new matter.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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There is no antecedent basis for the limitation “the plasmid of 2.1 kb in size isolated from *Lactobacillus plantarum*” in claim 1, from which the claim depends. This rejection can be overcome by using the indefinite article rather than the definite article in the phrase (*i.e.*, a plasmid of 2.1 kb...).

***Allowable Subject Matter***

Claims 1, 7-12 and 14 are allowed.


***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 571-272-0779. The examiner can normally be reached on Monday through Thursday 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Daniel M Sullivan, Ph.D.  
Examiner  
Art Unit 1636

  
DAVID GUZO  
PRIMARY EXAMINER